QUINN EMANUEL URQUHART & SULLIVAN, LLP
Kevin P.B. Johnson (Bar No. 177129)
kevinjohnson@quinnemanuel.com
Victoria F. Maroulis (Bar No. 202603)
victoriamaroulis@quinnemanuel.com
Andrew J. Bramhall (Bar No. 253115)
andrewbramhall@quinnemanuel.com
555 Twin Dolphin Drive, 5th Floor
Redwood Shores, California 94065-2139
Telephone: (650) 801-5000
Facsimile: (650) 801-5100

QUINN EMANUEL URQUHART & SULLIVAN, LLP
Valerie Lozano (Bar No. 260020)
valerielozano@quinnemanuel.com
865 Figueroa Street, 10th Floor
Los Angeles, California 90017
Telephone: (213) 443-3000
Facsimile: (213) 443-3100

QUINN EMANUEL URQUHART & SULLIVAN, LLP
Anne S. Toker (*pro hac vice*)
annetoker@quinnemanuel.com
51 Madison Avenue, 22nd Floor
New York, New York 10010-1601
Telephone: (650) 801-5000
Facsimile: (650) 801-5100

Attorneys for Defendant and Counterclaim-Plaintiff NATERA, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA,

SAN FRANCISCO DIVISION

GUARDANT HEALTH, INC.

Plaintiff and Counterclaim-Defendant,

vs.

NATERA, INC.

Defendant and Counterclaim-Plaintiff.

CASE NO. 3:21-CV-04062-EMC

NATERA, INC'S TRIAL BRIEF REGARDING EVIDENCE CONCERNING MEDICARE

Hearing:
Time:
Place:
Judge: Hon. Edward M. Chen

ARGUMENT

The Court should deny Guardant's motion to exclude additional evidence or argument concerning MolDX. The additional evidence that Natera intends to introduce relates to, *inter alia*, Guardant's concerns about Reveal's data and performance; MolDX's assessment of whether the Parikh study established performance characteristics of Reveal for surveillance use; and further evidence of Guardant's own comparisons of the Parikh and Reinert studies. This evidence is relevant to rebut Guardant's claims of false advertising, to rebut Guardant's allegations concerning Natera's state of mind, and to affirmatively prove that Guardant's advertisements are false and misleading. Guardant has introduced copious testimony concerning both Guardant's and Natera's communications with MolDX, and Natera should be allowed to introduce its own additional evidence on the same topic.

Contrary to Guardant's argument, Natera has never contended, and will not contend, that Guardant's communications with MolDX constitute "advertising" or form the basis for an affirmative claim under the Lanham Act.[1] And plainly Natera does not intend to introduce evidence or argument that Natera's actions caused delay in Guardant's Medicare coverage. Accordingly, this evidence is not precluded by the Court's ruling on MIL No. 2 (which *Natera* filed about Medicare reimbursement "delay" Guardant alleges was caused by Natera) and will not confuse the jury.

For the reasons set forth herein, the evidence in question is highly relevant to Natera's claims and defenses and should not be precluded.

I. EVIDENCE CONCERNING MOLDX IS RELEVANT TO REBUT GUARDANT'S CLAIMS ABOUT NATERA'S ALLEGED STATE OF MIND

Evidence of Guardant's interactions with MolDX is relevant to rebut Guardant's arguments about Natera's alleged state of mind with respect to Natera's submissions to MolDX. Guardant has openly accused Natera of trying to deny Guardant Medicare coverage for Reveal. Evidence

[1] To the extent Guardant is concerned about jury confusion, Natera would agree to a limiting instruction that neither party is contending in this case that communications with MolDX constitute false advertising under the Lanham Act.

concerning Guardant's interactions with MolDX, and MolDX's views of the data provided by Guardant, is directly relevant to rebutting these allegations.

Guardant has repeatedly offered evidence and arguments suggesting that Natera's actions in submitting comparisons of data to MolDX reflect Natera's state of mind that it was trying to harm Guardant, and that the information Natera presented was false. *See, e.g.*, Trial Tr. Day 2 at 202:11-12 ("The second part of the war was to ***lie to Medicare***, behind the scenes, about Reveal."); 204:7-10 ("While Guardant was presenting the research proving Reveal's positive performance, Natera had secret discussions with Medicare to convince them to deny coverage."); 206:17-19 ("So Natera's claims to Medicare ***were false in 2021 and they're still false today***."); Trial Tr. Day 4 at 746:6-9 ("We clearly learned that, you know, they were emailing the Medicare directors misinformation about Reveal"). Natera should be permitted to introduce evidence that it was not lying or presenting false information to Medicare because the issues it raised with respect to the Parikh data were true and its actions were justified. As the Court noted, ***if*** the statements by Natera to MolDX "were false claims, it goes to state of mind." Trial Tr., Day 2 at 226:17-18. It follows that if the claims were not false, then Natera did not have the state of mind that Guardant is suggesting.

Natera has and will introduce evidence that it was reasonable for Natera to raise questions with MolDX about deficiencies in Guardant's data because Guardant itself acknowledged these deficiencies in the data. Likewise, the fact that MolDX raised questions about Guardant's data also suggests that Natera's claims were not false because independent experts at MolDX raised similar questions with the data and declined to grant surveillance approval based on the Parikh study data. And, as discussed below, Guardant did not receive coverage for Reveal for surveillance use, which further confirms that the claims that Natera made to MolDX (and in its ads) about a lack of data supporting surveillance use were, in fact, true.

II. EVIDENCE RELATING TO MOLDX IS RELEVANT TO SHOW THAT GUARDANT'S ADVERTISEMENTS ARE FALSE AND MISLEADING

Guardant has repeatedly mislead the jury about the scope of Medicare coverage that it received for Reveal, claiming that MolDX approved Reveal without exception. *See, e.g.*, Trial Tr.,

Day 2 at 206:14-19 ("Well, Medicare's internal experts, who are neutral, were paying attention. They considered Natera's argument, including many of the same attacks Natera will repeat to you, and they rejected them. They approved Reveal for Medicare coverage."). By doing so, Guardant has suggested, implied and inferred that Natera was wrong to raise questions about the Parikh study data, that Natera's actions caused a delay in coverage, and that Guardant was ultimately vindicated when MolDX approved Reveal. *See* Trial Tr. Day 4 at 746:6-9, 747:13-15, 756:23-24 ("We clearly learned that, you know, they were emailing the Medicare directors misinformation about Reveal"; "we had delays in Medicare and that was known by the street"; "Q: Did Medicare ultimately approve Reveal [] for Medicare coverage? A: Yes."). This story is highly misleading because it leaves out a significant fact – MolDX did not approve Reveal for use in the surveillance setting. That is relevant both to Natera's affirmative claims that Guardant's ads claiming performance in the surveillance setting are false, and also to rebut Guardant's arguments about Natera's state of mind in raising questions with Medicare.

Natera asserts that Guardant's ads claiming 91% sensitivity in the surveillance setting are false and misleading, and are not supported by the Parikh study. Natera has introduced evidence that Guardant internally recognized it did not have sufficient data to support claims about Reveal's sensitivity and specificity in the surveillance setting. *See, e.g.*, TX-559 ("[W]e cannot say that with blood draws every 3-4 months in the surveillance setting the tests sensitivity will be 91%. We have not done this analysis with Guardant Reveal."). Guardant nevertheless pushed forward with the Parikh study, despite its data gaps, because it needed to try to obtain Medicare coverage as soon as possible to avoid falling behind Natera.

MolDX likewise rcognized this deficiency in Guardant's data and, as a result, has not approved Reveal for surveillance use. TX-612 at 4. Guardant has argued that MolDX has "internal experts, who are neutral" and who were paying attention. Trial Tr., Day 2 at 206:14-19. Natera agrees. And the recognition of the gap in Guardant's data by those neutral, independent experts at MolDX is highly relevant to show that Guardant does not have the data to support the claims it is making in its ads, in the same way that Guardant's own admissions about the gap in its data are relevant. By attempting to exclude evidence that Reveal was not approved for surveillance use,

Guardant is attempting to leave the jury with the false impression that MolDX approved Reveal for all uses, thereby purportedly blessing the sufficiency of Guardant's data in both adjuvant and surveillance settings and undermining Natera's position. In fact, the opposite is true. MolDX agreed that the Parikh study does not support Guardant's performance claims in the surveillance setting and to date has not approved the test in that setting. That fact is relevant to prove Natera's false advertising claim, and also to rebut Guardant's allegations about Natera's alleged state of mind – i.e., that Natera was allegedly making false claims to MolDX.

Evidence related to MolDX is also highly relevant to show Guardant's state of mind in continuing to disseminate its false advertisements about the performance of Reveal despite being aware of (and sharing) concerns about Reveal's data. Specifically, the evidence Guardant seeks to exclude shows at a minimum that Guardant knew the conclusion of MolDX assessment as to whether the Parikh study established performance of Reveal for surveillance use, and Guardant itself had concerns about Reveal's data and performance. *See* TX-612 at 1, 3, 5.

III. GUARDANT'S COMPARISON OF PARIKH AND REINERT FOR MOLDX IS RELEVANT TO REBUT GUARDANT'S CLAIMS OF FALSE ADVERTISING

Natera has introduced evidence that at least as early as November 2020 Guardant chose to directly compare data from the Reinert study with data from the Parikh study in order to support Guardant's request for Medicare coverage. *See, e.g.*, TX-585 at p. 17. This evidence directly contradicts Guardant's false advertising allegations premised on an argument that these two studies cannot be directly compared because it is an "apples-to-oranges" comparison. Long before any of Natera's ads compared data from these two studies, Guardant itself was comparing data from the studies, side-by-side, without any caveats about supposed differences in sample volumes, scanning frequencies, or patient populations. Not only is this evidence from which a jury could conclude that it was reasonable, and not misleading, to directly compare data from the two studies, but it also goes to the credibility of Guardant's witnesses who have repeatedly claimed that direct comparison of

the studies would be a misleading apples-to-oranges comparison.[2]

Guardant argues that it was required by MolDX to make that comparison. But Guardant was not required to submit anything to MolDX at all. And although Guardant was required to show comparable performance to Signatera once it decided to seek coverage for Reveal, the evidence shows that Guardant was not required to use the Parikh study to do so. *See* Trial Tr., Day 2 at 384:6-12 ("And MolDX didn't require you to use the Parikh study. They didn't tell you you have to use the Parikh study; right? A. They did not, no."). Rather, Guardant ***chose*** to rely on the Parikh study, the study closest in time to publication, for comparison with the Reinert study, and designed the study to be as close as possible for precisely this reason. Thus, if it was not false or misleading for Guardant to compare the data from these studies side-by-side, the jury can likewise conclude that it was not false and misleading for Natera to do so.

Guardant also argues that its comparisons of the studies with MolDX are not advertising. Natera agrees and has never suggested otherwise. Indeed, it would make no sense for Natera to argue in this case that Guardant's presentations to MolDX are advertisements as Natera does not believe that the comparisons were false or misleading. Natera's point is that the side-by-side comparison of the data in Natera's ads and the side-by-side comparisons in Guardant's presentations to MolDX are true and accurate. Guardant, on the other hand, is claiming that one comparison is false while the other is not. That inconsistency on the part of Guardant is highly relevant to the rebuttal of Guardant's claims in this case.

IV. THE COURT'S RULING ON NATERA'S MOTION IN LIMINE NO. 2 DOES NOT PRECLUDE THE FOREGOING EVIDENCE

The Court ruled in connection with Natera's motion *in limine* No. 2 that Natera's statements to MolDX are not actionable under the Lanham Act and, therefore, *Guardant* could not use those statements to argue that Natera caused delay in approval of Medicare that resulted in Guardant losing

[2] Guardant complains about Natera's questioning of Dr. Odegard about TX-585 (Guardant's presentation to MolDX), but it was Guardant who introduced TX-585 into evidence during Dr. Odegard's direct examination.

profits. Dkt. 509 at 7. As Guardant acknowledges (Dkt. 798 at 2), the Court's decision on Natera's MIL No. 2 did not prevent the introduction of any and all evidence concerning MolDX. Dkt. 509 at 9. Relying on the Court's ruling, Guardant has repeatedly introduced evidence that Natera allegedly tried to prevent Reveal from receiving Medicare coverage. *See, e.g.*, Trial Tr., Day 4 at 745-746 ("Q. Did you learn, after filing this case, that Natera had tried to prevent Reveal from being covered by Medicare? A. Yeah."); Trial Tr., Day 2 at 202:11-12 ("The second part of the war was to lie to Medicare, behind the scenes, about Reveal."); Trial Tr., Day 3 at 532:18-23("Q. So even before the commercial launch of Reveal, you and Dr. Aleshin were already thinking of how you could interfere with Guardant Health's ability to get coverage from Medicare; right? A. We wanted to make sure Medicare was evaluating the evidence appropriately."). And Guardant has indicated that they intend to continue introducing such evidence with other witnesses, including, e.g., documents they have disclosed for use with Solomon Moshkevich. *See, e.g.*, TX-221 (internal Natera email concerning whether Reveal meets MolDX criteria for coverage).

Just as there are relevant purposes for which Guardant may introduce evidence relating to MolDX, there are likewise relevant purposes for which Natera may introduce such evidence, including the purposes discussed above. Guardant's position seems to be, however, that while it is free to introduce evidence concerning Natera's actions with respect to MolDX to show Natera's state of mind, Natera cannot introduce any evidence at all concerning Guardant's actions with respect to MolDX, even when the documents are internal Guardant communications acknowledging deficiencies in the Parikh study. *See, e.g.*, TX-612. There is no basis for such an inconsistent treatment of the evidence, and to impose such a lop-sided rule at this trial would be highly unfair and prejudicial.

The Court's ruling on MIL No. 2 was based on the fact that there is no legally cognizable action for violation of the Lanham Act based on Natera's statements to MolDX. In this respect, Guardant's repeated claims that Natera's evidence concerning MolDX is purportedly "opening the door" makes no sense. No matter what evidence Natera presents, Guardant cannot claim Lanham Act liability for Natera's statements to MolDX because, as the Court already found, those statements were not made to consumers. And to the extent that Guardant is suggesting that the evidence opens

the door to Guardant arguing that Natera caused its delay in Medicare coverage (even though that cannot result in any actionable harm), Guardant has already opened that door itself by repeatedly ignoring the Court's MIL order. *See, e.g.*, 204:7-10 ("While Guardant was presenting the research proving Reveal's positive performance, Natera had secret discussions with Medicare to convince them to deny coverage."); Trial Tr., Day 3 at 532:18-23 ("Q. So even before the commercial launch of Reveal, you and Dr. Aleshin were already thinking of how you could interfere with Guardant Health's ability to get coverage from Medicare; right? A. We wanted to make sure Medicare was evaluating the evidence appropriately."); Trial Tr., Day 3 at 533:3-6 ("Your goal here was to keep Guardant Health from getting coverage by Medicare for its Reveal test? A. My goal was to have MolDX educated and evaluate the evidence in the right way."); Trial Tr., Day 5 ("Q. Part of your strategy to salt Guardant's launch, your words, included trying to prevent it from getting Medicare coverage; right?").

The Court's order did not preclude, nor should it preclude, any and all evidence concerning MolDX. MIL 2 was Natera's motion, and Natera never argued to exclude all such evidence—whether in motion practice or at trial. Guardant's attempt to turn the Court's ruling that Natera's statements to MolDX are not legally actionable on its head to preclude Natera from presenting highly relevant evidence should be denied.

CONCLUSION

Natera respectfully requests the Court grant the relief sought herein.

DATED: November 13, 2024

QUINN EMANUEL URQUHART & SULLIVAN, LLP

By /s/ *Kevin P.B. Johnson*
Kevin P.B. Johnson
Attorneys for NATERA, INC., a Delaware corporation, Defendant and Counterclaim Plaintiff

ATTESTATION

I, Andrew J. Bramhall, am the ECF user whose ID and password are being used to file the above document. In compliance with Local Rule 5-1(i)(3), I hereby attest that Kevin P.B. Johnson has concurred in the filing of the above document.

By */s/ Andrew J. Bramhall*
Andrew J. Bramhall